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NRC ACMUI SUBCOMMITTEE ON TRAINING AND EXPERIENCE REQUIREMENTS

INTRODUCTION

A revision of 10 CFR Part 35, Medical Use of Byproduct Material, was published on April 24, 2002 (Federal Register Vol. 67(79) 20371-20397). The revision contains new training and experience requirements for individuals to become authorized as a radiation safety officer (RSO), authorized medical physicist (AMP), authorized nuclear pharmacist (ANP), and authorized user (AU). These new requirements provide several options for individuals to become authorized. One option is for individuals to be certified by a specialty board whose certification process includes all the requirements in an alternate pathway. The alternate pathway includes specified numbers of hours of training and written certification signed by a preceptor that the individual has satisfactorily completed the training requirements and has achieved a level of competency sufficient to function independently as an RSO, AMP, ANP, or AU. Currently, most specialty boards do not require candidates to meet these specific requirements.

The Advisory Committee on Medical Uses of Isotopes (ACMUI) appointed a subcommittee on training and experience requirements to develop recommendations that would restore board certification as the default pathway for individuals to become authorized as RSO, AMP, or AU. The ACMUI subcommittee has developed the following drafts of new training and experience requirements.

The draft rule language in these draft recommendations is based on the following assumptions:

(1) Currently accepted boards should be listed explicitly in the regulations;
(2) To facilitate addition of future certification mechanisms to the T&E qualification process without rulemaking initiatives, criteria should be included in the rule to provide a basis for recognizing such boards;
(3) It is expected that the currently accepted boards will meet the criteria in (2);
(4) The preceptor concept should be modified to become documentation of successful completion of a training program rather than a testament to clinical competence; and;
(5) Specific training should be required for certain new devices or modalities. This training is considered to be a separate requirement that is decoupled from the core training and supervised experience.

These drafts and any public input will serve as a basis for discussion at a meeting of the subcommittee on June 21 in Rockville, Maryland. The subcommittee will develop recommendations from the June 21 meeting to the full ACMUI.

## § 35.50 Training for Radiation Safety Officer

Except as provided in § 35.57, the licensee shall require the an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.24 to be an individual who –

(a) Is certified by:
- (1) American Board of Health Physics in Comprehensive Health Physics;
- (2) American Board of Medical Physics in Medical Health Physics;
- (3) American Board of Radiology;
- (4) American Board of Nuclear Medicine;
- (5) American Board of Science in Nuclear Medicine;
- (6) Board of Pharmaceutical Specialties in Nuclear Pharmacy;
- (7) American Board of Medical Physics in Radiation Oncology Physics
- (8) American Board of Medical Physics in Diagnostic Radiology Physics
- (9) Royal College of Physicians and Surgeons of Canada in Nuclear Medicine;
- (10) American Osteopathic Board of Radiology;
- (11) American Osteopathic Board of Nuclear Medicine; or

(b) Is certified by a specialty board whose certification has been recognized by the Commission and requires all diplomates:
- (1) To hold a bachelors or graduate degree from an accredited college or university in physical science or biological science with a minimum of 20 college credits in physical science;
- (2) To have six or more years of responsible professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics;
- (3) To provide a written certification from the supervising physicist or RSO that the individual has completed the training and experience described in paragraph (b)(2) of this section; and
- (4) To pass an examination administered by diplomates of the specialty board, which evaluate knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, and radiation biology; or

(c) (1) Has completed a structured educational program consisting of 200 hours of didactic training in the following areas--
- (A) Radiation physics and instrumentation;
- (B) Radiation protection;
- (C) Mathematics pertaining to the use and measurement of radioactivity;
- (D) Radiation biology; and

(2) Has one year of full-time radiation safety experience under the supervision of an individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes similar types(s) of use(s) of byproduct material involving the following--
- (A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
(C) Securing and controlling byproduct material;
(D) Using administrative controls to avoid mistakes in the administration of byproduct materials;
(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
(F) Using emergency procedures to control byproduct material; and
(G) Disposing of byproduct material; or

(d) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities.

(e) In addition to meeting the requirements of (a), (b), (c), or (d) of this section, the licensee shall require a Radiation Safety Officer to have training in the radiation safety, regulatory issues, emergency procedures, and proposed clinical procedures of any modality for which the licensee seeks authorization. This training requirement may be satisfied by satisfactorily completing training that is supervised by an Authorized Medical Physicist or Radiation Safety Officer authorized for the modality for which the licensee is seeking authorization.

**§ 35.51 Training for an Authorized Medical Physicist.**

Except as provided in § 35.57, the licensee shall require the authorized medical physicist to be an individual who –

(a) Is certified by the American Board of Radiology in--
(1) Therapeutic radiological physics;
(2) Roentgen ray and gamma ray physics;
(3) X-ray and radium physics; or
(5) Radiological physics; or

(b) Is certified by the American Board of Medical Physics in radiation oncology physics; or

(c) Is certified by a specialty board in radiation oncology physics (for clarity and simplification, these subfields (or relevant portion thereof) of the specialty boards in (a) and (b) of this section will henceforth be referred to as “radiation oncology physics”) whose certification has been recognized by the Commission and requires all diplomates;
(1) To hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an institution accredited by a regional accrediting body
(2) To have two years of full-time supervised practical training and/or supervised radiation oncology physics experience that
(i) Is supervised by medical physicist who is certified in radiation oncology physics by the board in question.

(ii) Occurs in a clinical radiation oncology facility that provides megavoltage external beam therapy and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 35.400 or 35.600

(3) To successfully passes an examination administered by diplomates of the certification board in question that assesses knowledge and competence in clinical radiation oncology, radiation safety, calibration, quality assurance, treatment planning for external beam therapy, brachytherapy and stereotactic radiosurgery.

Or

(d)

(1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an institution accredited by a regional accrediting body

(2) Has completed 1 year of full-time training in radiation oncology physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the modality in which the individual is seeking authorization in a clinical radiation oncology facility providing megavoltage external beam therapy and brachytherapy services that includes the tasks listed in §§ 35.67, 35.433, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, and 35.652, as applicable

(3) Has obtained written certification from the supervising medical physicist that the individual has satisfactorily completed the training and experience described in paragraph (b)(2) of this section and identifies the byproduct material modalities included.

(e) In addition to meeting the requirements of (a), (b), (c), or (d) of this section, an authorized medical physicist must have training in the modality for which authorization is sought that includes device operation, safety procedures, clinical use, and operation of treatment planning system that is equivalent to instruction provided by the vendor to new customers. This training requirement may be satisfied by satisfactorily completing a training program provided by the vendor or by training supervised by an AMP authorized for the modality in which the individual is seeking authorization.

**Sec. 35.190 Training for uptake, dilution, and excretion studies.**

Except as provided in Sec. 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under Sec. 35.100 to be a physician who—

(a) Is certified in--

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology by the American Board of Radiology;

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada;

(4) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or

(b) Is certified by a medical specialty board whose certification process:

(1) Includes all of the requirements in paragraph (d)(1) of this section;

(2) Requires successful completion with a passing grade of written and oral exams administered by diplomates of the certification board that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; and

(3) Has been recognized by the Commission; or

(c) Is an authorized user under Secs. 35.290 or 35.390 or equivalent Agreement State requirements; or

(d)(1) Has completed 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include--

(i) Classroom and laboratory training in the following areas--

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in Sec. 35.190, Sec. 35.290, or Sec. 35.390 or equivalent Agreement State requirements, involving--

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in Secs. 35.190, 35.290, or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (d)(1) of this section.

**Sec. 35.290 Training for imaging and localization studies.**

Except as provided in Sec. 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under Sec. 35.200 to be a physician who--

(a) Is certified in--

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology by the American Board of Radiology;

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada;

(5) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine;

(6) Nuclear cardiology by the Certification Board of Nuclear Cardiology; or

(b) Is certified by a medical specialty board whose certification process:

(1) Includes all of the requirements in paragraph (d)(1) of this section;

(2) Requires successful completion with a passing grade of written and oral exams administered by diplomates of the certification board that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; and

(3) Has been recognized by the Commission; or

(c) Is an authorized user under Sec. 35.390 or equivalent Agreement State requirements; or

(d)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a minimum--

(i) Classroom and laboratory training in the following areas--

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use;

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in Secs. 35.290 or 35.390 or equivalent Agreement State requirements, including–

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
(F) Administering dosages of radioactive drugs to patients or human research subjects; and
(G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in Secs. 35.290 or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (d)(1) of this section.

**Sec. 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.**

Except as provided in Sec. 35.57, the licensee shall require an authorized user of a sealed source for a use authorized under Sec. 35.600 to be a physician who—

(a)(1) Is certified by a medical specialty board whose certification process requires successful completion of a three year residency program in radiation oncology approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education;

(2) Has passed an examination that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance and clinical use of stereotactic radiosurgery, high and low dose-rate brachytherapy, and external beam therapy; and

(3) Whose certification has been recognized by the Commission; or

(b)(1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes--

(i) 200 hours of classroom and laboratory training in the following areas--

(A) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics pertaining to the use and measurement of radioactivity; and
(D) Radiation biology; and

(iii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in Sec. 35.690 or equivalent Agreement State requirements at a medical institution, involving—

(A) Reviewing full calibration measurements and periodic spot-checks;
(B) Preparing treatment plans and calculating treatment doses and times;

(C) Using administrative controls to prevent a medical event involving the use of byproduct material;
(D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
(E) Checking and using survey meters; and
(F) Selecting the proper dose and how it is to be administered; and

*(2)* Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in Sec. 35.690 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

*(3)* Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section for each type of therapeutic medical unit for which authorized user status is requested. The written certification must be signed by a preceptor authorized user who meets the requirements in Sec. 35.690 (or equivalent Agreement State requirements for an authorized user) for each type of therapeutic medical unit for which authorized user status is requested.

(c) Boards currently recognized by the Commission to meet all the requirements of paragraph (a) of this section include the American Board of Radiology, the American Osteopathic Board of Radiology, British Royal College of Radiology, and the Canadian Royal College.

(d) In addition to meeting the requirements of paragraphs (a) or (b) of this section, an authorized user of a sealed source authorized under 35.600 must have training in the modality for which authorization is sought. This includes training in device operation, safety procedures, and clinical use that is equivalent to that instruction provided by the vendor to new customers. This training requirement may be satisfied by satisfactorily completing the training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the modality in which the individual is seeking authorization.